Gambling with nature.

Why gene drives are not a viable route to nature conservation

Gene drives, a potentially dangerous application of genetic engineering, enable forced inheritance and species manipulation. With proposed uses in disease vector and invasive species control, as well as agriculture, the main risks and challenges of gene drives relate to uncontrollability, regulation, and ethical concerns. Current scientific knowledge is not sufficient to allow it to be used cautiously and ethically. This article discusses gene drives as a conservation tool, concluding it is not a viable option for halting global biodiversity loss.

Barbara Couto Pilz, Naomi Kosmehl, Benedikt Härlin

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Gene drives are perhaps the most dangerous application of genetic engineering. In practice, engineered gene drives are an attempt to change the constitution of a species by means of forced inheritance. This technology could be used to lead entire species to extinction or to replace wild populations with genetically modified organisms.

According to Mendel's principles of natural inheritance, a specific trait or mutation can be passed to future generations at a 50% chance. However, with the introduction of a gene drive system, the chance of inheriting the engineered trait could be closer to a 100%. This would happen even if the trait were detrimental to the species' survival (Brandt et al. 2019).

From a technological point of view, the genome editing tool, Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR) associated with the protein Cas9, is used to identify a target DNA sequence where it can introduce a change in an organism's DNA. The Cas9 induces a double strand break in the target sequence of the DNA and the gene drive technology takes advantage of the cell's natural repair mechanism. By attempting to repair the damage, cells will generally copy the gene drive cassette into the next (opposite) chromosome (figure 1). As a result, all subsequent reproductive cells will carry this gene drive on both chromosomes, meaning all offspring will also carry a copy (Henn and Imken 2021).

Some examples of future proposed applications of gene drives include the eradication of organisms acting as disease vectors, the removal of invasive species from ecosystems, and the control of so-called pests in agriculture.

However, such technological fixes do not come risk free. "Automating" the genetic engineering of organisms via heredity means opening the possibility for forced mutations to disseminate autonomously across generations without the possibility of containment. In practical terms, genetically engineering organisms in the wild means moving engineering processes from laboratories to ecosystems. Among other concerns, this development would hinder controllability, risk assessment, regulation, as well as raise immense societal and ethical challenges (Sirinathsinghji 2019b).

Gene drive organisms have not yet been released into the environment. Nevertheless, the excitement of some scientists, researchers, philanthropists, and practitioners proposing this technology as a panacea for tackling invasive species and disease control is alarming and should be addressed. A one-sided account of the supposed benefits of gene drive organisms overlooks the potential irreversible damage gene drives could cause in the environment and all ecosystems – should they work, or not.

To balance the discourse and stimulate discussion, this article presents some of the reasons why gene drive organisms should not be considered and/or prioritised as a viable route to nature conservation and proposes ways forward into managing this technology.

This article is written by Save our Seeds (SOS), a non-profit organisation promoting the access to and the diversity of seeds, as well as the preservation of sustainable agriculture practices. The work of SOS on gene drives focuses on upholding the voices of affected communities in global policy development processes and bringing critical, socioeconomic, science, and other knowledge system-based perspectives to the development of technological fixes. As a civil society organisation dedicated to the prudent oversight of emerging technologies, we underscore the imperative need for prioritising precaution, safety, ethics, and systemic solutions over technological "quick fixes".

Barbara Couto Pilz | Save Our Seeds | Campaign Manager | Berlin | DE | pilz@saveourseeds.org

Naomi Kosmehl (corresponding author) | Save Our Seeds | Public Relations Lead | Berlin | DE | kosmehl@saveourseeds.org

Benedikt Härlin | Save Our Seeds | Head of Office | Berlin | DE | haerlin@zs-l.de

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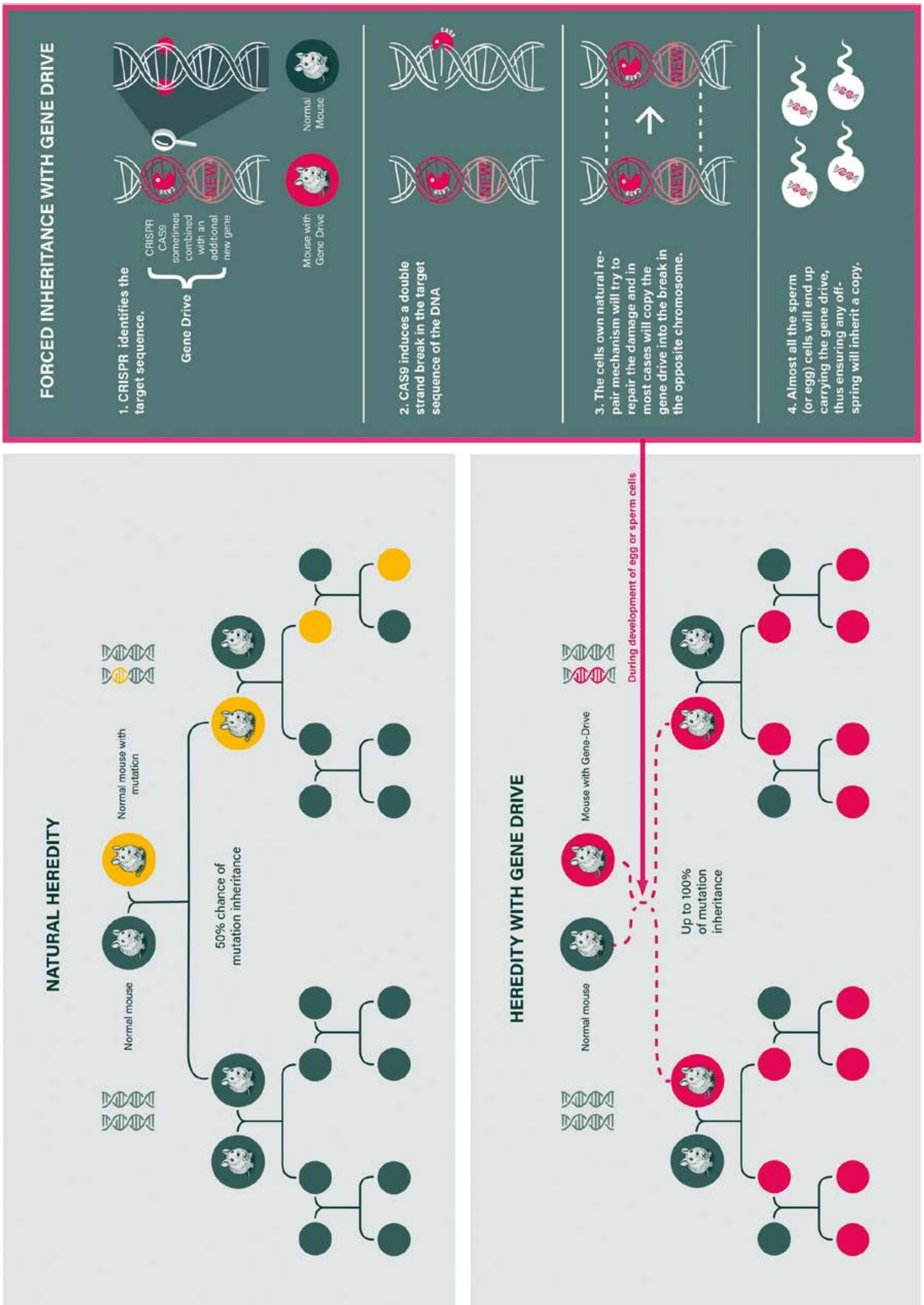

FIGURE 1: An explanation of how a CRISPR gene drive works versus the natural heredity of genes in mice populations. Source: Save Our Seeds.

Gene drives and nature conservation

One of the most advanced and compelling potential applications for gene drives in nature conservation is the suppression of invasive mice populations on islands (McFarlane et al. 2023). Islands are hotspots for biodiversity loss, and mice are often one of the main drivers of this loss. Introducing mice manipulated to carry gene drives could potentially offer a solution to this problem through, for example, changing the sex determination, fertility, or viability of the mice population (Godwin et al. 2019). However, there are several environmental, ethical, and political concerns with this approach. First of all, mice, especially house mice *(Mus musculus)*, are highly adaptable and mobile, inhabiting all continents and many islands (Brandt et al. 2019). This makes it highly likely that, contrary to the belief that islands are contained spaces, gene drive mice could spread from target islands to adjacent areas.

Gierus et al. (2022) estimate that it would take 20 years to suppress large mouse populations using gene drives. Such a long-term presence raises concerns about modified mice reaching mainland areas, potentially eliminating wild species (Esvelt and Gemmell 2017). Mice escaping, island proximity, as well as mating and horizontal gene transfer contamination (i.e., the transfer of genetic material between organisms other than by reproduction) pose additional risks (Russell et al. 2008, Brandt et al. 2019). Finally, gene drives' potential to cross species (Connolly et al. 2023) could lead to an increased chance of unforeseen molecular or ecological consequences over time.

Beyond mice, numerous other species worldwide are considered invasive and a threat to biodiversity, and gene drives have been proposed as a management solution (e.g., Dearden et al. 2018, Faber et al. 2021, Lester et al. 2020). An essential question is how to decide when, where, and which species to eradicate using gene drives, while considering their cumulative, associated risks.

Furthermore, gene drives are being extensively considered for agricultural use. The patent specification from Esvelt and Smidler (2015) lists over 100 weeds and more than 300 agricultural pests that could be controlled by gene drives in the future for the purpose of "agricultural safety and sustainability". Wells and Steinbrecher (2023a, b) conducted two horizon-scanning exercises which examine gene drives developed for 32 insect targets and 42 non-insect targets. Many of these drives aimed to suppress or eradicate species, particularly in the agricultural sector. The researchers raised the question of whether gene drives are becoming a form of "species-specific pesticides" (Wells and Steinbrecher 2023b).

Social and environmental consequences of using gene drives in agriculture (which also apply to other uses) could include potential harm to non-target species and ecosystem disruptions; threats to food security if crucial pollinators, natural predators, or beneficial species are lost; and regulatory and governance hurdles due to the transboundary nature of gene drives (Sirinathsinghji 2019a, Lalyer et al. 2021).

Gene drive research remains largely compartmentalised, with publications and projects typically concentrating on individual species without considering the environmental interactions or the ethical and socioeconomic repercussions. Recent scientific exploration of the interconnectedness of organisms within ecosystems indicated that current knowledge is insufficient to allow for the safe deployment of gene drive organisms into the environment. Even small genetic modifications can impact gene expression, phenotypes, behaviour, and entire ecosystems (Matsuoka and Monteiro 2018, Simon et al. 2018, Lalyer et al. 2021). The rapidly growing field of invasion biology highlights the need for interdisciplinary research to understand species interconnectedness and the impacts of alterations (Ricciardi et al. 2021).

In light of the factors mentioned in this section, it seems radically disingenuous and dangerous to pretend that the potential impacts of eradicating or irreversibly modifying populations and entire species of organisms can be comprehensively predicted over time and space. Our stance is that the path forward in gene drive development must be navigated with a deep respect for the intricate balances within ecosystems (and societies), taking into account their complexities.

Irreversible, uncontrollable, unpredictable

Some of the main potential ecological risks posed by the release of gene drive organisms include their irreversible, uncontrollable, and unpredictable character. This section aims to bring illustrative examples of how these characteristics could negatively affect the environment and human life.

Once released into the environment, there is currently no viable method to reverse or neutralise the impact of gene drives on the target population and any sexually compatible species. Although genetic mechanisms for reversing, limiting, or eliminating gene drives have been proposed, there are no detailed analyses of their expected dynamics (Vella et al. 2017). Coupled with their ability to spread quickly and relentlessly through or beyond a population, gene drives must be considered an uncontrollable force in the environment. The complex interactions between genetic sequences, organisms, and the environment make it difficult to predict the full extent of the ecological consequences of releasing gene drives.

Furthermore, gene drives may spread to non-target species through interbreeding or even horizontal gene transfer, which can cause unintended ecological impacts (EFSA Panel on Genetically Modified Organisms 2013). The loss or alteration of any species could result in the disruption of crucial ecological functions, such as pollination, seed dispersal, and nutrient cycling (Rao and Larsen 2010). In addition, the release of gene drive organisms could create hybrid organisms (Boëte 2018, Evans et al. 2019) that may be more virulent or resistant to existing control measures. This could lead to a race of genetic engineering, where the development of countermeasures must keep pace with the creation of new threats.

Gene drives could disrupt socioeconomic dynamics of communities reliant on specific species. For example, gene drives targeting certain fish species could impact fishing communities if these species or their predators are key sources of income and food. Also, unintentional effects of gene drive organisms on pollinator populations, and other species, could impact agricultural yields and destabilise ecosystems. Since gene drives could create cascading impacts in both managed and unmanaged ecosystems, they hold the capacity to influence other species and entire food chains (Lalyer et al. 2021). Consequently, affecting the foundations of rural community livelihoods.

Notwithstanding, complex concerns regarding gene drives go far beyond the potential consequences and emerge long before the technology is released into the environment. They start at the point of research, testing, and decision-making. The next section aims at providing a brief description of some of the ethical considerations linked to gene drive research and development (for a more detailed examination of the ethical considerations, see Eser 2024, in this issue).

Before irreversible decisions are made, a global moratorium on the release of gene drive organisms into nature, including field trials, is immediately necessary to allow for a thorough investigation of potential risks and the development of satisfactory governance frameworks.

Lack of responsibility in gene drive research and development

The power to edit and manipulate the genetic makeup of entire populations raises ethical questions about who has the right to make such decisions and how these decisions should be made. Releasing gene drive organisms into the environment is, in essence, playing with the building blocks of life. This raises concerns about the potential abuse of this technology by powerful entities and the possibility of irreparable harm caused by unregulated experimentation or release.

Various organisations and institutions, both public and private, are currently spearheading research on gene drives across the globe. Leading actors in the field include military agencies such as the US Defense Advanced Research Projects Agency (DARPA), academic institutions, biotech companies, and philanthropic organisations, such as the Bill and Melinda Gates Foundation through the research consortium Target Malaria. Other key players in the field include the Genetic Biocontrol of Invasive Rodents (GBIRd), Imperial College London, Broad Institute, Harvard University, University of North Carolina, and the University of California San Diego, among others.

While institutions in the Global North lead most research and development around gene drive technology, most testing grounds for these risky technologies are planned to take place in the Global South, particularly in Sub-Saharan Africa. This means that communities in the region have become passive recipients of externally imposed so-called solutions (Mentz-Lagrange and Swanepoel 2022). Such practices reinforce historical patterns of exploitation and perpetuate the inequitable power dynamics between the Global North and South. By imposing untested, risky technologies on African communities, researchers are violating the principles of consent, autonomy, and justice that are fundamental to ethical research (Mentz-Lagrange and Sirinathsinghji 2020, Taitingfong 2021).

Due to the fact that gene drive development is often concentrated in the hands of well-funded institutions, corporations, and philanthropic organisations from the Global North, this leads to concerns about the equitable distribution of benefits and control over the technology. Unequal ownership and influence in gene drive research is a result of failing to engage in transparent, evidence-based decision-making.

As an organisation committed to upholding the rights of potentially affected communities, SOS believes that engaging diverse stakeholders and right holders (including indigenous peoples, local communities, and researchers from the Global South) in equitable partnerships and decision-making processes is crucial to attempt to develop gene drive technology responsibly. The principle of Free Prior and Informed Consent (FPIC) ensures that communities potentially affected by the release of gene drives have the right to be informed, to participate in decision-making processes, and have their decisions respected (OHCHR 2013). Furthermore, stringent regulations and risk assessment frameworks must be in place to guide the testing and deployment of gene drives, guarding against potential harm to ecosystems and human populations, and considering cross-boundary movements. The recently adopted *Kunming-Montreal Global Biodiversity Framework* was an attempt to establish relevant biodiversity related regulation, including the topic of synthetic biology, but fell short in providing a robust structure (Lovera 2022). There are currently no comprehensive international legal frameworks regulating research and transparency in either the intentional or unintentional release of gene drives into the environment. Since gene drives have the potential to spread across jurisdictional boundaries globally, only international and legally binding regulations can address the risks of their release into the environment comprehensively (Ching and Lin 2019).

Another concern is that commercial and financial interests are skewing gene drive research, leading to the prioritisation of

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profit over public welfare and the environment. As seen in the *Gene Drive Files* (ETC Group 2017), substantial funding and resources are often directed towards research and development efforts, increasing the pressure to generate successful outcomes and justify investments. This creates a biased research environment that downplays risks, overlooks alternative solutions, and undermines the rights of indigenous peoples and local communities (ETC Group 2017).

A biased research environment creates distrust and, in the case of gene drive technology, requires utmost caution. With just a few gene drive organisms, a scientist could potentially change the entire makeup of a species, giving them the power to alter nature on a fundamental level (see *Gene Drive Film* 2020 for further details). Technologies like gene drives could launch a paradigm shift in humanity's understanding of its relationship with and control over nature, opening the possibility for large-scale, permanent, genetic engineering of the wild. Accordingly, as a complex and controversial topic, research and communication about gene drives needs to be transparent, encompassing multiple points of view, and avoiding language that is often used as a marketing tool or propaganda.

One example of how language has been distorted to portray gene drives in an exclusively positive light is the repeated use of the term "innovation" by gene drive proponents (e.g., Tarimo 2021, Target Malaria 2023, Wetaya 2023). The concept of "innovation" is often associated with positive ideas such as progress, improvement, development, and discovery. In this case, it suggests the introduction of something that could bring about positive change and generate enthusiasm, while disregarding the associated risks and nuances.

Finally, a biased research environment can be an obstacle to making the issue of gene drives accessible to non-scientific audiences, and ulterior motives may be hidden and difficult to uncover. It may contribute to creating a false sense of security and overconfidence in the technology, which could lead to premature implementation and unforeseen consequences. It is the responsibility of all those engaged in gene drive research, advocacy, and debate to prevent the spread of misinformation. Our civil society viewpoint is that in addition to being scientifically rigorous, research practices need to be socially and environmentally responsible.

A comprehensive and ethically grounded approach is lacking at every stage of gene drive development to address the complex concerns that emerge long before their release into the environment. Caution, responsibility, and the consideration of alternatives should take priority over hasty implementation. Current research and development efforts are racing to implement gene drives as an immediate technology fix to biodiversity loss, disease control, and agricultural management without carefully considering the potential ecological and ethical risks associated with their release (e.g., APET 2018, Target Malaria 2020, ACB 2022). This is a shallow and dangerous approach to addressing environmental challenges and demonstrates why gene drives should not be considered a viable route to nature conservation.

Conclusion: Time to tap out

General scientific understanding of genetic and epigenetic microbiology and ecology is still limited. As such, there are currently no adequate scientific means to assess the evolutionary impacts of gene drives over time and space. Beyond the potential for gene drives to fail, accumulate risks, and affect non-target species, different ethical concepts of human societies regarding the due respect for nature, other living organisms, their evolution, and the complex interaction amongst them raise questions about where we draw the line in, for example, eradicating species.

The emergence of gene drive propositions in sectors like agribusiness raises concerns about their use as targeted pesticides. Moreover, there is a lack of interdisciplinary and responsible research to fully comprehend the complex interconnectedness of species and the effects of genetic modifications. Accordingly, it is risky to assume species can be eradicated or irreversibly altered, while accurately predicting potential impacts. Therefore, environmental release of gene drives should not be viewed as a viable route to conservation.

The environmental release of gene drives could only be viable in the long-term, in any form or purpose, if a set of fundamental unresolved governance and ethical issues were to be concretely addressed. Before irreversible decisions are made, a global moratorium on the release of gene drive organisms into nature, including field trials, is immediately necessary to allow for a thorough investigation of potential risks and the development of satisfactory governance frameworks.

In addition, before any release is considered it would be necessary to establish globally uniform safety standards and a global notification scheme for research on the topic. This should come in conjunction with a global prohibition of the development of gene drive organisms with potential for military use.

Considering what is discussed above we recommend that scientific research efforts should focus on advancing more stable, promising, safe alternatives to invasive species control, species resilience, and nature conservation in general. Any further research on gene drives should be based on the precautionary principle and include interdisciplinary collaboration integrating insights from ecology, ethics, sociology, and other relevant fields, in order to comprehensively and transparently assess this technology.

When it comes to policy making, SOS believes that robust and stringent global regulatory frameworks should be put in place through inclusive and meaningful stakeholder engagement. This includes a precautionary global moratorium on the release of gene drive organisms into nature, as well as rigorous technology assessment processes that consider socioeconomical, cultural, and ethical implications of gene drive technology.

In advocating for systemic, holistic solutions, we, as civil society representatives committed to rigorous scientific practice, emphasize the importance of addressing the root causes of biodiversity loss and public health issues, rather than merely mitigating their symptoms through unsafe, ineffective, and ethically controversial technological interventions. Accordingly, the potential known and unknown risks, as well as ethical implications of gene drives demand a collective "tap out" from the high-stakes gamble of environmental release. Nature (and biodiversity) conservation is not a game and therefore avoiding significant losses is not a choice but a requirement.

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Barbara Couto Pilz
2023 to 2024 member of the latest multidisciplinary Ad Hoc Technical Expert Group (Montreal, CA) on synthetic biology of the UN Convention on Biodiversity. Campaign manager leading the international policy work on gene drives at Save Our Seeds, DE. Research interests: international relations, intercultural conflict management in agricultural settings.

Naomi Kosmehl
Masters in human rights and humanitarian action from the Paris Institute of Political Studies, FR, specializing in the right to food. Expertise in national and international policy making, promoting sustainable food systems and safeguarding the environment. Research interests: gene drives, genetically modified organisms (GMOs), and synthetic biology, emphasizing food sovereignty and environmental protection.

Benedikt Härlin
Co-founder of numerous newspapers, including *die tageszeitung.* 1984 to 1989 member of the European Parliament. 1993 to 2001 head of the Greenpeace office in Berlin, DE, creator of the campaign on genetically modified organisms (GMOs) for Greenpeace International. Since 2002, head of the Foundation on Future Farming office in Berlin, the international campaign Save Our Seeds, and GMO-Free Europe.